

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



United States
Environmental Protection
Agency

Office of Pesticide Programs

Antimicrobials Division (AD)

April 10, 2015

DP BARCODE: 424059
MRID: 49467400, 49467401, and 49467402
SUBJECT: Synergex
REG. NO.: 1677-ELN
DOCUMENT TYPE: Product Chemistry Review
Manufacturing-use [] OR End-use Product [X]

INGREDIENTS:

<u>PC Code(s)</u>	<u>CAS Number</u>	<u>Active Ingredient(s)</u>
063201	79-21-0	Ethaneperoxoic acid
063209	33734-57-5	Peroxyoctanoic acid
000595	7722-84-1	Hydrogen peroxide

TEST LAB: Ecolab
SUBMITTER: Ecolab
GUIDELINE: Group A and B Product Chemistry
ORGANIZATION: AD\PSB\CTT
REVIEWER: Lynette T. Umez-Eronini
APPROVED BY: Karen P. Hicks
APPROVED DATE: April 9, 2015
COMMENT: This product is for use on hard, non-porous food and non-food contact surfaces.

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MEMORANDUM

SUBJECT: Product Chemistry Review for EPA Reg. 1677-ELN
Product Name: Synergex
DP Barcode: 424059

DATE DUE: April 13, 2015

FROM: Lynette T. Umez-Eronini, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Lynette T. Umez-Eronini

THRU: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Karen Hicks
4/10/15

TO: Seiichi Murasaki PM #31/Elizabeth Watkins
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Ecolab Inc.

CODE: A540 New Product; Non-Fast Track

PRODUCT FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Hydrogen Peroxide	10.70
Peroxyoctanoic Acid	0.63
Peroxyacetic Acid	2.38
<u>Other Ingredient(s):</u>	<u>86.29</u>
Total:	100.00

BACKGROUND:

The registrant, Ecolab Inc., has submitted an application for registration of a new integrated end-use product called Synergex. The product is a food and non-food contact sanitizer.

The following documents were reviewed:

1. Cover letter (from the registrant to EPA, 10/20/2014.
2. EPA Application for Pesticide (8570-1), 10/20/2014.
3. Basic and Alternate #1, #2, and #3 Confidential Statements of Formula (CSFs), 10/20/2014.
4. Revised Basic and Alternate #1, #2, and #3 CSFs, 4/7/2015.
5. Certification with Respect to Citation of Data (8570-34) for the three active ingredients, 10/20/2014.
6. Proposed product label, 10/20/2014.
7. End-Use and Generic Data Matrices (Agency copy) (8570-36), June 9, 2014.
8. Data Matrix (Agency copy) (8570-36) for the Synergex, 10/20/2014, 4 pages.
9. Data Matrix (Agency copy) (8570-36) for each of the three active ingredients, August 14, 2014, 1 page each.
10. Rationale for revising the upper and lower certified limits, "Determination of the acceptance ranges for Project Spartan II," August 10, 2014.
- 11.

49467400	Ecolab, Inc. (2014) Submission of Product Chemistry, Efficacy and Toxicity Data in Support of the Application for Registration of Synergex. Transmittal of 31 Studies.
49467401	Davis, B. (2014) KX-6228: Chemical Characterization. Project Number: 1300148, 1300149. Unpublished study prepared by Ecolab Schuman Campus. 66p
49467402	Davis, B. (2014) KX-6228: Accelerated Storage Stability. Project Number: 1300149. Unpublished study prepared by Ecolab Schuman Campus. 19p.

FINDINGS:

1. The nominal concentration of each active ingredient on the CSFs is consistent with the label.
2. Support for wider certified limits for the active ingredients and some of the inert ingredients is provided and is acceptable.
3. All ingredients in the formulation are approved for use in pesticide formulations.
4. Group A product chemistry data requirements applicable to end-use products have been met (see MRID# 49467401 and Table A below).

5. Group B product chemistry data requirements applicable to end-use products have been met (see MRID# 49467401 and 49467402 and Table B below).

CONCLUSION:

Product Science Branch of Antimicrobials Division finds the Basic and Alternate #1, #2, and #3 CSFs, dated October 20, 2014 to be acceptable. Also Group A and B Product Chemistry data requirements have been met.

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- | | | |
|--|---------|--------|
| • Non-integrated formulation system | Yes [] | No [X] |
| • Are all TGAIs used registered? | Yes [] | No [X] |
| • Integrated formulation system | Yes [X] | No [] |
| • If "ME-TOO," specify EPA Reg. No. of existing product: | | |

The product is cleared for food use under 40 CFR §180.940 and §180.950.

Yes [X] No []

c. Physical state of product:

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.

Yes [X] No []

e. The NCs and CLs are acceptable.
(They should read as follows in f below.)

Yes [X] No []

f. Active ingredient	<u>NC(%)</u>	<u>LCL(%)</u>	<u>UCL(%)</u>
Hydrogen Peroxide	10.70	9.75	11.55
Peroxyoctanoic Acid	0.63	0.49	0.78
Peroxyacetic Acid	2.38	2.04	2.72

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
Yes [] No [] Not applicable [X]
- Have all impurities of $\geq 0.1\%$ in the product been identified?
Yes [] No [] Not applicable [X]

II PRODUCT LABEL

a. The active ingredient statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes ☒ No ☐

b. The formula contains one of the following:

- | | | |
|--|------------------------------|--|
| • 10% or more of a petroleum distillate: | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • 1.0% or more of methyl alcohol: | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • sodium nitrite at any level: | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • a toxic List 1 inert at any level: | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • arsenic in any form: | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this?

Yes ☐ No ☐ Not applicable ☒

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.

Yes ☐ No ☐ Not applicable ☒

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.

Yes ☒ No ☐

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).

Yes ☐ No ☐

Table A:
Product Chemistry (Series 830, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity ¹	A	49467401
830.1600 Description of Materials	A	49467401
830.1620 Production Process ²	A	49467401
830.1650 Formulation Process ³	A	49467401
830.1670 Formation of Impurities ⁴	A	49467401
830.1700 Preliminary Analysis ⁵	A	49467401
830.1750 Certified Limits ⁶	A	49467401
830.1800 Enforcement Analytical Method ⁷	A	49467401
830.1900 Submittal of Samples	A	49467401

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

¹See Confidential Appendix A for additional information.

²For MP/EP products produced by an integrated formulation system.

³For products from a TGA1 or MP.

⁴May be waived unless actual/possible impurities are of toxicological concern.

⁵Five batch analysis required for products produced by an integrated formulation system.

⁶If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

⁷Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	NA		
830.6303 Physical State	A	Liquid	49467401
830.6304 Odor	N/A		
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NA		
830.6314 Oxidation/Reduction; Chemical Incompatibility	A	This product is known to be a strong oxidizing agent.	49467401
830.6315 Flammability/Flame Extension	A	Product contains acetic acid, a combustible liquid.	49467401
830.6316 Explodability	A	This product does not contain any explodable ingredients.	
830.6317 Storage Stability (Accelerated)	A	Included in separate study: (Accelerated) Ecolab GLP study 1300149	49467401
830.6319 Miscibility ¹	A	Product is not intended for use with oil or a non-polar solvent.	49467401
830.6320 Corrosion Characteristics (Accelerated)	A	Included in separate study: (Accelerated) Ecolab GLP study 1300149	49467402
830.6321 Dielectric Breakdown Voltage	A	Product is not a nonconductant liquid and will not be used around electrical equipment.	49467402
830.7000 pH ² (Average)	A	1.59	49467401
830.7050 UV/Visible Absorption	NA		
830.7100 Viscosity (Average)	A	5.08 cps	49467401
830.7200 Melting Point/Melting Range	NA		
830.7220 Boiling Point/Boiling Range	NA		
830.7300 Density/Relative Density/Bulk Density	A	1.203 (Average Specific Gravity)	49467401
830.7370 Dissociation Constants in Water	NA		
830.7550/830.7560/830.7570 Partition Coefficient	NA		
830.7840/830.7860 Water Solubility	NA		

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.7950 Vapor Pressure	NA		

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

¹If product is an emulsifiable liquid

²If product is dispersible with water